

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	Examiner: MacNeill, Elizabeth
David HUNG)	
)	Group Art Unit: 3767
Serial No. 09/912,499)	
)	
Filed: 07/26/2001)	Attorney Docket No.: 12.018011
)	
For: METHODS, AND DEVICES FOR)	
DIAGNOSIS OF PRECANCER AND)	
CANCER IN BREAST MILK DUCTS)	

**PETITION UNDER 37 C.F.R. §1.181 REQUESTING WITHDRAWAL OF
ABANDONMENT AND REINSTATEMENT OF APPLICATION**

Mail Stop Petitions
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

September 11, 2007

Dear Sir:

Applicants hereby petition under 37 CFR §1.181 to request withdrawal of the holding of abandonment, and reinstatement of the above-referenced patent application. The Notice of Abandonment, mailed June 8, 2007, states that the application became abandoned due to Applicant's failure to timely file a proper response to the Office letter mailed on June 15, 2006 [EXHIBIT A].

1. Response

Prior to receiving the Notice of Abandonment, the last communication the Applicant had received from the United States Patent and Trademark Office was an Examiner's Answer dated June 15, 2006 [EXHIBIT B] which was filed in response to Applicant's Appeal Brief which was filed February 15, 2006. The Applicant is not aware of any requirement of the USPTO which requires a response to be filed to an Examiner's Answer. Repeated phone calls to Supervisory Patent Examiner, Kevin C. Sirmons has not resulted in any explanation for or the withdrawal of the Notice of Abandonment. It is regrettable that the Applicant must now petition the USPTO and respectfully request the official withdrawal of the Notice of Abandonment for the above referenced application, and reinstatement of the Appeal Brief so that proceedings before the BPAI may resume.

2. Petition Fee

Although no fee is believed to be required, the Commissioner is hereby authorized to charge any fee which may be required to Deposit Account No. 502855.

3. Verified Statement

I further declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States

Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Customer No. 0000 38732

By: 

Theodore Allen
Registration No. 41,578
Cytoc Corporation
250 Campus Drive
Marlborough, MA 01752
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Customer Number :

EXHIBIT A



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
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12.018011

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,499	07/26/2001	David Hung	05284.00006	6261

38732 7590 06/08/2007
CYTYC CORPORATION
250 CAMPUS DRIVE
MARLBOROUGH, MA 01752

EXAMINER

MACNEILL, ELIZABETH

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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06/08/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of Abandonment

Application No.

09/912,499

Examiner

Elizabeth R. MacNeill

Applicant(s)

HUNG, DAVID

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on 15 June 2006.
 - (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
 - (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.
(A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
 - (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
 - (d) ☒ No reply has been received.
2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
 - (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
 - (b) ☐ The submitted fee of \$_____ is insufficient. A balance of \$_____ is due.
The issue fee required by 37 CFR 1.18 is \$_____. The publication fee, if required by 37 CFR 1.18(d), is \$_____.
 - (c) ☐ The issue fee and publication fee, if applicable, has not been received.
3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
 - (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
 - (b) ☐ No corrected drawings have been received.
4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.
5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.
6. ☐ The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.
7. ☐ The reason(s) below:

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons

Elizabeth MacNeill

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.

EXHIBIT B



UNITED STATES PATENT AND TRADEMARK OFFICE

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09/912,499	07/26/2001	David Hung	05284.00096	6261

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CYTYC CORPORATION
250 CAMPUS DRIVE
MARLBOROUGH, MA 01752

Received
Cytoc Corporation

JUN 23 2006

Darry Pattinson
Legal Department



EXAMINER

HAN, MARK K

ART UNIT PAPER NUMBER

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DATE MAILED: 06/15/2006

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07/26/2001

David Hung

~~05284.00006~~

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Application No.

09/912,499

Examiner

Elizabeth R. MacNeill

Applicant(s)

HUNG, DAVID

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

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EXAMINER	
HAN, MARK K	
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/912,499
Filing Date: July 26, 2001
Appellant(s): HUNG, DAVID

MAILED
JUN 15 2006
Group 3700

Theodore R. Allen, Cytoc Corporation
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 15 February 2006 appealing from the Office action mailed 15 August 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,616,656	NICHOLSON et al.	10-1986
4,767,011	BUTLER	08-1988
4,947,842	MARCHOSKY et al.	08-1990
5,003,905	RAYNOR	04-1991
5,623,942	PESTES et al.	04-1997
6,101,635	JONES	08-2000
6,319,267	KURZ	11-2001
6,391,026	HUNG et al.	05-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,623,942 to Pestes et al. (hereinafter "Pestes").

Pestes discloses a flexible probe 12 having a diameter that is sized to access a breast duct and a distal portion being capable of contacting an interior lumen of a breast duct and retrieving a sample of the breast duct fluid from within the duct for analysis (distal end of 10), and wherein said probe is free of an opening through which a fluid from an external source can be introduced into said probe and pass through said probe into the duct when said probe is positioned within the breast duct (Fig. 1), and wherein said probe is rigid before entry into the breast duct, and flexible upon resistance into the duct (col. 2, lines 16-25 and 32-40); as to claims 2-6, (distal end of 10). As to claim 13, (nylon).

In support of the Examiner's position that Pestes discloses a flexible probe having a diameter that is sized to access a breast duct and a distal portion that is capable of contacting an interior lumen of a breast duct, the Examiner relies on the disclosure of U.S. Patent No. 6,391,026 to Hung et al. (hereinafter "Hung"). Hung discloses a catheter that is used to access a breast duct having an outer diameter of 0.8 mm (or 0.08 cm). See Figures 1-10B and col. 10, lines 54-63. Here, Pestes discloses a device that is capable accessing a breast duct that has an outer diameter of 0.035 inches (or 0.08 cm). Therefore, the Pestes device is capable of performing the function as set forth in claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3767

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 8, 10, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pestes in view of U.S. Patent No. 4,616,656 to Nicholson et al. (hereinafter "Nicholson").

Pestes discloses a device for collecting breast duct fluid substantially as claimed except for a means (marker/indicia) to measure a quality of the ductal fluid *in situ*. Nicholson discloses a means (marker/indicia) to measure a quality of the ductal fluid *in situ* (col. 4, lines 12-17). Therefore, It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the distal portion of Pestes with the means to measure a quality of the ductal fluid, as taught by Nicholson, for providing markings to indicate the depth of the device distal end when anchored. It is noted that Appellant indicates that such quality/means can comprise a marker (page 4, line 8).

Pestes discloses a device for collecting breast duct fluid substantially as claimed except for a probe diameter between 0.008 cm to about 0.045 cm. Pestes discloses a probe with a diameter of 0.08 cm. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to vary the diameter of the probe, since it would only involve a mere change in the size of a component. Additionally, Appellant has not disclosed that a diameter between 0.008 cm to about 0.045 cm provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Appellant's invention to perform equally well with a diameter of 0.08 cm. Therefore, such a change in size is considered to be well within the level of skill of the ordinary artisan.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pestes in view of U.S. Patent No. 4,947,842 to Marchosky et al. (hereinafter "Marchosky").

Pestes discloses the device substantially as claimed except for a coating of an anesthetic on the exterior of the probe. Marchosky discloses an anesthetic coating on the exterior of the probe.

Therefore, It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Pestes with the coating taught by Marchosky to relieve pain in the treatment of tumors particularly in the breast area (col. 5).

(10) Response to Argument

a. Pestes discloses every single element of independent claim 1.

In response to Appellant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a probe that is sufficiently rigid to enter through the sphincter of a breast duct, but flexible enough that the body will bend when it encounters resistance within the breast duct [Appeal Brief, p. 5, lines 2-5]) are not recited in the rejected claim(s). The claim language does not specify the degree of rigidity or flexibility that the Appellant suggests in the Appeal Brief. If the probe should be rigid enough to pass through a closed sphincter of a breast duct as opposed to one that is already opened or malfunctioning, then the claim language should specify such a limitation. Otherwise, such a limitation will not be read into the claims. The same argument is applicable to the flexibility of the probe. Appellant does not claim that the probe should be flexible enough that it will bend upon reaching a branch in the ductal passageway. The claim does not specify what type of resistance that the probe will encounter once inside the passageway (e.g. the wall of a normal

ductal passageway, the wall of a hardened ductal passageway, a lesion within the wall of the passageway (e.g. papilloma)). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

For these reasons, Pestes anticipates independent claim 1, and the rejection under 35 U.S.C. §102(b) must be sustained.

b. Pestes discloses the limitations of claim 13.

Appellant's claim 13 requires that the probe is made of a shape memory material. Pestes suggests fiberglass and nylon as materials for the probe. Fiberglass and nylon can be considered as shape memory materials. All that is required for something to have shape memory characteristics is the ability to return to its original shape when an external force that flexes the object, is removed. For example, a rod made of fiberglass or nylon will flex when a force is applied perpendicular to the length of the rod. When the force is removed, the rod will return to its original shape. U.S. Patent Nos. 4,767,011 to Butler and 5,003,905 to Raynor provide evidence that fiberglass may be manufactured to be highly flexible or rigid. U.S. Patent Nos. 6,101,635 to Jones and 6,319,267 to Kurz provide evidence that nylon may be manufacture to be highly flexible or rigid. These ranges of flexibility or rigidity of fiberglass and nylon show that devices may be manufactured to a sufficient rigidity such that it would exhibit shape memory qualities.

For these reasons, Pestes anticipates dependent claim 13, and the rejection under 35 U.S.C. §102(b) must be sustained.

c. The elements of claims 7, 8 and 10 are obvious over Pestes in view of Nicholson.

Appellant argues that Nicholson does not disclose a means to measure the quality of the ductal fluid. Claim 8, which is dependent from Claim 7, requires that a quality indicia is cell size. The markings provided by Nicholson are used to measure the depth of a breast lesion via mammogram. It is also possible that these markings provide a scale to measure an individual cell size. If cell size is an indicator of a quality of ductal fluid as suggested by Appellant's claim 8, then markings suggested by Nicholson is certainly a means to measure a qualitative aspect of ductal fluid.

For these reasons, claims 7, 8 and 10 are unpatentable over Pestes in view of Nicholson. The rejection under 35 U.S.C. §103(a) must be sustained.

d. The elements of claims 26 and 27 are obvious over Pestes.

In response to Appellant's argument that the Pestes reference is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the Pestes reference is in the field of devices used to collect fluid/cell samples. The only difference is in the location of where the samples are retrieved. A mere change in the size of a device to access a different area of the body is obvious to one of ordinary skill in the art and is unpatentable over Pestes.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

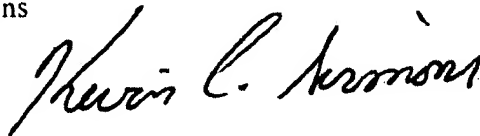
Respectfully submitted,



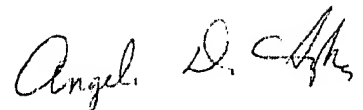
Mark Han
Patent Examiner
Art Unit 3767

Conferees:

Angela Sykes
Kevin Sirmons



KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER



ANGELA D. SYKES
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